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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/908,469	08/06/1997	MANUEL BACA	P1093P1	9546
9157	7590	10/28/2003	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			HELMS, LARRY RONALD	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

08/908,469

Applicant(s)

BACA ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 and 39-42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34, 35, 43-45, 48 and 50 is/are allowed.
- 6) ☒ Claim(s) 36-38, 46, 47, 49 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 42.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/03 has been entered.
2. Claims 1-51 are pending.  
  
Claim 34 has been amended and claims 43-51 have been added.
3. Claims 1-33, 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non elected inventions. Election was made without traverse in paper 7.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

6. The rejection of claims 34-38 under 35 U.S.C. 102(a) as being anticipated by Baca et al (The Journal of Biological Chemistry 272:10678-10684, 4/18/97, IDS #14) is withdrawn in view of the arguments presented and showing that Chen and Lowman are

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authors on the J. Mol. Biol reference which teaches affinity maturation which is in the specification and therefore the combination of the papers of JBC and J. Mol. Biol result in the claimed invention.

7. The rejection of claims 34-38 under 35 U.S.C. 102(f) is withdrawn in view of the arguments presented and showing that Chen and Lowman are authors on the J. Mol. Biol reference which teaches affinity maturation which is in the specification and therefore the combination of the papers of JBC and J. Mol. Biol result in the claimed invention.

8. The rejection of claims 34-38 under 35 U.S.C. 103(a) as being unpatentable over Ferrara et al (WO 94/10202, published 5/11/94) and further in view of Adair et al (WO 91/09967, published 7/11/91, IDS#4) and Yelton et al (The Journal of Immunology 155:1994-2004, 1995) is withdrawn in view of the amendments to the claims.

***The following are NEW GROUNDS of rejections***

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 36-38 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 36, as written, do not sufficiently distinguish cells over cells as they exists naturally because claim 36 does not particularly point out any non-naturally occurring differences between the claimed cells and the structure of naturally cells.

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The specification contemplates producing antibodies by homologous recombination and using mammalian cells (see pages 37 and 39). The method incorporates the nucleic acid into the genome of the mammal and as such when using human cells and recombinant vectors for homologous recombination this would result in a human cell with the antibody gene and thus could be introduced into a mammal including a human host.

In the absence of the hand of man, the naturally occurring cells are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" host cell or similar language would obviate this rejection.

### ***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 46-47, 49, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 46 is indefinite for reciting "heavy chain variable domain sequence of SEQ ID NO:125" because the exact meaning of the phrase is not clear. SEQ ID NO:125 is a CDRL3 not an entire variable domain. In addition it is a light chain CDR3 not a heavy chain.

b. Claim 47 is indefinite for reciting "light chain variable domain sequence of SEQ ID NO:124" because the sequence is a CDRL2 not an entire variable domain.

c. Claim 49 is indefinite for reciting "CDRH1 sequence of SEQ ID NO:126" because the sequence is an entire light chain variable domain not just a CDR sequence. Does the phrase mean that the variant has a CDRH1 in the sequence of SEQ ID NO:126 or does it mean that the entire variable domain is SEQ ID NO:126?

d. Claim 51 is indefinite for reciting "CDRH3 sequence of SEQ ID NO:127" because the sequence is an entire heavy chain variable domain not just a CDR sequence. Does the phrase mean that the variant has a CDRH3 in the sequence of SEQ ID NO:127 or does it mean that the entire variable domain is SEQ ID NO:127?

### ***Conclusions***

10. Claims 34-35, 43-45, 48, 50 are in condition for allowance.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00

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am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER